REMARKS

Initially, it is noted that the Examiner has indicated that claims 21-24 contain allowable subject matter. Applicant has rewritten dependent claim 21 in independent form. It is now believed that claim 21 is in proper form for allowance and such action is earnestly solicited. Claims 22-24 depend either directly or indirectly from independent claim 21 and further define a microfludic device not shown or suggested in the art. It is believed that claim 22-24 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

The Examiner has rejected claims 1-6 and 10-15 under 35 U.S.C. § 102(b) as being anticipated by van Lintel, U.S. Patent No. 5,224,843. Claims 1-2, 10-12 and 18 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Eckenhoff et al., U.S. Patent No. 4,552,561 and claims 1-3 and 10-12 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Couvillon, Jr. et al., U.S. Patent Application No. 2004/0068224. Claim 7 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over the van Lintel '843 patent; claims 8 and 16 have been rejected under the '843 patent in view Beebe et al., U.S. Patent No. 6,523,559; and claim 18 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over the Couvillon, Jr. et al. '224 application in view of Connelly et al, U.S. Patent No. 6,689,100. As hereinafter described, applicant has amended the rejected claims to more particularly define the invention for which protection is sought. Applicant respectfully requests reconsideration in view of the following comments.

Claim 1 defines a microfluidic device for delivering a drug to an individual. The individual has physiological fluid therein. The microfluidic device includes a reservoir for receiving the drug therein and an output needle having an input in communication with the reservoir and an output receivable with the individual. A pressure source is engageable with the reservoir and has an adjustable configuration directly responsive to a predetermined fluid between a first configuration and a second configuration for urging the drug from the reservoir to the output needle. The pressure source is isolated from the physiological fluid of

the individual. As hereinafter described, none of the cited references shows or suggests a pressure source having an adjustable configuration directly responsive to a predetermined fluid when the pressure source is isolated from the physiological fluids of an individual.

The van Lintel '843 patent is directed to a micro pump used for an *in situ* administration of medications in which the patient wears the micro pump on their person or possibly implanted in the patient's body. The pump includes a base layer that includes inlet and outlet channels for the pump. The outlet channel is connected to a reservoir containing the liquid to be pumped. The inlet channel is connected to an injection needle or the like. A wafer is mounted to the upper surface of the base wafer and has a thickness that can be deformed by a control amount element. In the depicted embodiment, the control element is a piezoelectric disc operatively connected to an alternative voltage generator. A pumping channel is defined between the wafer and the base layer. When a voltage is applied to the piezoelectric disc, the disc flexes causing the wafer to bend inward toward the base layer. The pressure in the pumping chamber rises thereby actuating an opening in the outlet valve so as to force the medication through the outlet connector. It is noted that the van Lintel '843 patent is entirely silent as to the use of a predetermined fluid to change the configuration of the pressure source. As pointed out by the Examiner, more specifically, nothing in the '843 patent requires the pressure source to directly respond to a predetermined fluid as required by independent claim 1. Consequently, it is believed that independent claim 1 defines over the van Lintel '843 patent.

The Eckenhoff et al. '561 patent discloses a self-contained body mounted pump assembly for continuously administering a therapeutic agent parenterally. The pump has a transparent top through which the contents can be seen. The pump assembly is driven by a fluid imbibing, preferably osmotic pump and contains its own source of actuating fluid. In operation, a drug is provided in displacement chamber 25. When ready for use, hydrogel 18 fills the volume defined between snap ring 13 and the surface of pump 11. Liquid from the hydrogel diffuses through semi-permeable wall 16 and dissolves the osmagent in pump 11 to a saturated solution. A steady state is reached when the saturated solution formed within

pump 11 is emitted steadily to outlet 17 to cause displacement partition 10 to be steadily forced into chamber 25, thereby urging the contents thereof through passageway 20 and cannula or needle 22. Hence, unlike the microfluidic device of independent claim 1, the pressure source does not change configuration directly in response to a predetermined fluid. The pressure source is the predetermined fluid. This structure differs significantly from the structure of the microfluidic device of claim 1. Hence, it is believed that the independent claim 1 defines over the '561 patent.

The Couvillion, Jr. et al. '224 application is directed to a drug delivery pump apparatus that incorporates an expandable and contractable enclosure having an interior volume that defines a medication reservoir. One or more electroactive polymer actuators act to reduce the interior volume of the contractable and expandable enclosure based upon received control signals. Hence, just like the van Lintel '843 patent, the pressure source does not directly respond to the predetermined fluid. Hence, it is believed that independent claim 1 defines over the '224 application.

Finally, applicant has submitted herewith an Information Disclosure Statement identifying Ron et al., U.S. Patent No. 5,935,593. The '593 patent discloses a system for delivery of a biologically active substance into an environment. First and second chambers are separated by a movable partition. The first chamber includes a polymer gel network which undergoes the volume change in response to an environmental condition such as pH. The first compartment includes a screen or membrane for confining the polymer gel network while allowing communication with fluid in an environment. A second compartment contains a biologically active compound or drug which is delivered to the environment through an orifice in the second compartment. Hence, unlike the microfluidic device of independent claim 1, the pump source, namely, the polymer gel is not isolated from the physiological fluid in the environment (in other words, the physiological fluids of the individual) as required by independent claim 1. Hence, it is believed that independent claim 1 defines over the '593 patent.

In view of the foregoing, applicant believes that independent claim 1 defines over the cited references and is in proper form for allowance. Claims 2-8 further define a microfluidic device not shown or suggested in the prior art. It is believed that claims 2-8 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

Claim 10 defines a microfluidic device for delivering a drug to an individual. The individual having physiological fluids therein. The microfluidic device includes a body defining a reservoir for receiving the drug therein and a conduit. The conduit has an input communicating with the reservoir and an output. An output needle has a input receivable in the body to communicate with the output of the conduit and an output extending outside of the body for insertion in the individual. A pressure source is engageable with the reservoir and directly responsive to a predetermined fluid urging the drug from the reservoir to the output needle. The pressure source is isolated from the physiological fluids of the individual.

As heretofore described, none of the cited references shows or suggests a microfluidic device wherein the pressure source is directly responsive to a predetermined fluid and is isolated from the physiological fluids of the individuals. Such a structure is entirely absent from the cited references. Consequently, it is believed that independent claim 10 is in proper form for allowance and such action is earnestly solicited.

Claims 11-16 depend either directly or indirectly from independent claim 10 and further define a microfludic device not shown or suggested in the prior art. It is believed that claims 11-16 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

Claim 18 defines a microfluidic device for delivering a drug to an individual. The individual has physiological fluids therein. The microfluidic device includes a body defining a reservoir for receiving the drug and an output needle having input and communication with the reservoir and an output receivable within the individual. An adhesive is provided for

affixing the body to the individual. The microfluidic device also includes a pressure source that includes a hydrogel member expandable in direct response to exposure to a predetermined physiological property. The hydrogel member is engageable with the reservoir and urges the drug from the reservoir through the output needle as the hydrogel member expands. The pressure source is isolated from the physiological fluids of the individual.

As heretofore described in the Eckenhoff et al. '561 patent, the hydrogel does not expand, but releases a liquid component that diffuses through a semi-permeable wall to dissolve the osmotgen. Hence, nothing in the '561 patent shows or suggests utilizing an expandable hydrogel as a pressure source. Further, unlike the drug delivery device disclosed in the '593 patent wherein the hydrogel shares a common environment with the environment in which the drug is dispensed, the hydrogel is isolated from such environment in independent claim 18. Hence, it is believed that independent claim 18 defines over the '561 and '593 patents and is in proper form for allowance.

Applicant believes that the present application with claims 1-8, 10-16, 18 and 21-24 is in proper form for allowance and such action is earnestly solicited. A check in the amount of $180.00 is enclosed for the fee associated with the filing of the Information Disclosure Statement. Applicant believes that there are no other fees associated with this Amendment. However, the Director is hereby authorized to charge payment of any other fees associated with this communication or credit any overpayment to Deposit Account No. 50-1170.

Respectfully submitted,

By _____
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